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Daubert and the EPA: An Evidentiary Approach to Reviewing Agency Determinations of Risk

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Regulation of environmental risk poses serious problems for affected parties. The Environmental Protection Agency ("EPA") often bases its policies on risk assessments that overestimate dangers, rest on questionable assumptions, and suffer from scientific inaccuracies. When affected parties challenge these policies, judges must exhibit great deference to the agency's determinations rather than remedying the ultimate problem. Under the current scheme of judicial deference, agencies—especially the EPA—lack the incentive to base their decisions on the best scientific information available.

This Comment explores the problems the EPA faces when making regulatory decisions in the shadow of scientific uncertainty. It advocates reducing that uncertainty by applying the *Daubert* standard for admissibility of expert scientific testimony to judicial review of agency decisions.[1] Part I examines the problems agencies face in regulating environmental risks. Part II discusses the current state of judicial review of administrative decisions, including the specific difficulties courts face in balancing deference to an agency's specialized decisions against oversight of those decisions' rationality. Finally, Part III argues that applying the *Daubert* standard to judicial review of agency determinations would create an important check on agency decisionmaking, while still allowing the EPA the discretion it requires to make effective environmental policy.

I. Problems With Environmental Risk Regulation

A. What is Risk Regulation?

Environmental agencies like the EPA exist to protect the public against environmental harms. Often, however, by the time

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[1] *Daubert v Merrell Dow Pharmaceuticals, Inc.*, 509 US 579 (1993).

a harm has occurred, the agency can only clean up the mess. Therefore, agencies seek to regulate substances or situations that pose a risk of harm, to prevent the harm from occurring in the first place. Risk regulation consists of two steps: risk assessment and risk-benefit analysis. During risk assessment, agencies determine exactly how much danger a threat poses to the environment. Once they have made the risk assessment, agencies move to risk-benefit analysis, which measures the beneficial effects of a regulation against the costs of imposing it.

This Comment addresses problems that pervade the first step: risk assessment. Commentators usually divide risk assessment into four stages.[2] First, the EPA performs a hazard identification, which determines whether exposure to a potentially toxic agent threatens human health.[3] Second, it performs a dose-response assessment, which relates the dose of the toxin to its adverse health effects.[4] Third, it performs an exposure assessment, which estimates the possible intensity, frequency, and duration of human exposure to the toxin.[5] Finally, the EPA generates a risk characterization, which estimates the incidence of adverse health effects under various exposure conditions.[6]

B. Problems

1. *Credibility.*

Environmental risk regulation suffers from a number of administrative difficulties.[7] First, agency risk assessments face a credibility problem because they have overregulated some risks to the point of absurdity. Agencies frequently make determinations that, while logically based on the initial assumptions, seem

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[2] National Research Council, *Risk Assessment in the Federal Government: Managing the Process*, 18-28 (National Academy 1983) (*"Managing the Process"*). For an excellent discussion of these stages from an evidentiary perspective, see Vern R. Walker, *Evidentiary Difficulties with Quantitative Risk Assessments*, 14 Colum J Envir L 469, 472-74 (1989). See also Junius C. McElveen and Chris Amantea, *Legislating Risk Assessment*, 63 U Cin L Rev 1553, 1580-89 (1995) (explaining stages of risk assessment).

[3] National Research Council, *Managing the Process* at 20-23 (cited in note 2).

[4] Id at 23-27.

[5] Id at 27-28.

[6] Id at 28-29.

[7] See, generally, John S. Applegate, *A Beginning and Not an End in Itself: The Role of Risk Assessment in Environmental Decision-Making*, 63 U Cin L Rev 1643 (1995); Mark Eliot Shere, *The Myth of Meaningful Risk Assessment*, 19 Harv Envir L Rev 409 (1995); Lynn R. Goldman, *Environmental Risk Assessment and National Policy: Keeping the Process Fair, Effective and Affordable*, 63 U Cin L Rev 1533 (1995); Donald T. Hornstein, *Reclaiming Environmental Law: A Normative Critique of Comparative Risk Analysis*, 92 Colum L Rev 562 (1992).

so patently ridiculous to non-regulators as to invite extensive public criticism and even judicial reversal.[8] For example, in *United States v Ottati & Goss, Inc.*,[9] the EPA based its risk assessments for a Superfund hazardous waste cleanup on the assumption that small children would eat contaminated dirt 245 days a year for three years.[10] Another striking example involves risk assessments for a proposed cleanup by the Fernald Environmental Project, which used a baseline of a "naked, dirt-eating farmer" to measure possible exposure damage from hazardous materials.[11] These absurdities result from the overly cautious assumptions agencies use when calculating the possibility of a given risk occurring.[12]

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[8] See Stephen Breyer, *Breaking the Vicious Circle: Toward Effective Risk Regulation* 11-19 (Harvard 1993) ("*Breaking the Vicious Circle*"); Applegate, 63 U Cin L Rev 1643 (cited in note 7).

[9] 900 F2d 429, 441 (1st Cir 1990) (Breyer). *Ottati & Goss* upheld the District Court's refusal to grant the injunctive relief requested by the EPA requiring a polluter to clean up a Superfund waste site. Id at 432. The First Circuit could explicitly overrule the EPA's risk assessment in this case, instead of only commenting unfavorably, because it had already held that when an agency seeks injunctive relief, the court is not bound by the Administrative Procedure Act's "arbitrary and capricious" standard. Id, citing 5 USC § 706 (1994).

[10] Id at 441. Justice Breyer has made this case infamous in his book *Breaking the Vicious Circle* at 11-12 (cited in note 8). However, Breyer may have overstated the absurdity of the assumption. Small children playing in a field may get dirt on their hands, and if they fail to wash properly before eating, could actually ingest small quantities. See Victor B. Flatt, *Should the Circle Be Unbroken?: A Review of the Hon. Stephen Breyer's* Breaking the Vicious Circle: Toward Effective Risk Regulation, 24 Envir L Rev 1707, 1711 (1994). The controversy over Breyer's characterization does not diminish the agency credibility problem, however. If a federal judge may effectively overrule an environmental agency because she perceives absurdity, then agencies must convince judges of the scientific validity of their assessments.

[11] Applegate, 63 U Cin L Rev at 1653-54 (cited in note 7). The assessment, in this case used by a citizen task force assisting the EPA, assumed resident proximity to the contaminated soil, full body exposure, and incidental consumption of toxic dirt. Like the dirt-eating child, a farmer who gets dirt on her hands and in her clothes may be "naked" for the purposes of soil exposure, but the public still perceives such standards as overly cautious. Applegate notes that the "naked, dirt-eating farmer" standard, while itself extremely conservative, proved much less stringent than the EPA's proposed risk standard. Id at 1653.

[12] Often, agencies rely on conservative assumptions as a response to the uncertainty they face in regulating unknown risks. By itself, a cautious assumption may justify some small additional cost from the regulation it generates. The problem results when agencies must make more than just one assumption per risk assessment. At that point each error on the side of caution magnifies the effect of the other errors. See, for example, Breyer, *Breaking the Vicious Circle* at 42-50 (cited in note 8); John D. Graham, *Improving Chemical Risk Assessment*, 14 Regulation 14, 15 (No. 4, 1991); Bernard D. Goldstein, *Risk Assessment and the Interface Between Science and Law*, 14 Colum J Envir L 343, 352-53 (1989). But see Adam M. Finkel, *Is Risk Assessment Really Too Conservative?: Revising the Revisionists*, 14 Colum J Envir L 427 (1989).

Absurdity alone is not a dramatic problem, but it does have several implications for agency credibility.[13] Because agencies do not exist in a political vacuum, credibility remains important to an agency's ability to enact good policy. If the public loses confidence in an agency's ability to make policy decisions rationally, the legislative or executive branch may step in to force rationality upon it—a cure which could prove worse than the disease.[14]

2. *Inconsistency.*

Even if an agency does not suffer from diminished credibility, it may still face an inconsistency problem. As any analysis of regulation will demonstrate, agencies frequently value similar risks differently.[15] However, different agencies will sometimes treat even the exact same risks differently.[16] For example, when examining the cancer risks from pesticides on food, the EPA produced an estimated risk of cancer mortality ten times greater than the Food and Drug Administration's ("FDA").[17] In a world of limited resources, valuing equivalent (or even identical) risks differently invites misallocation. Assuming that one agency has determined the proper level of risk, and that both agencies must regulate the risk to reduce it to its optimal level, the second agency is either over- or under-regulating. If the agency under-regulates, lives are lost that could have been saved by more regulation. If it over-regulates, it attacks a threat after the marginal benefits of the spending no longer justify the costs of additional regulation.[18] Like those that reach absurd results, agencies that inconsistently assess environmental risks invite not only public

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[13] See, for example, Breyer, *Breaking the Vicious Circle* at 50-51 (cited in note 8) (discussing difficulties agencies face in fighting public opinion regarding risks).

[14] See, for example, the failed congressional attempts to mandate risk assessment for environmental regulations discussed in McElveen and Amantea, 63 U Cin L Rev at 1589-96 (cited in note 2).

[15] See, for example, W. Kip Viscusi, *The Value of Risks to Life and Health*, 31 J Econ Literature 1912, 1926-27 table 2 (1993).

[16] Wendy E. Wagner, *The Science Charade in Toxic Risk Regulation*, 96 Colum L Rev 1613 (1995); Howard Latin, *Good Science, Bad Regulation, and Toxic Risk Assessment*, 5 Yale J Reg 89, 108 (1988). See also Michael Gough, *How Much Cancer Can the EPA Regulate Away?*, 10 Risk Analysis 1, 4 table 2 (1990) (comparing EPA and FDA treatment of similar cancer risks).

[17] Gough, 10 Risk Analysis at 4 table 2 (cited in note 16). The EPA method of assessing cancer mortality risk estimated 3,000 cancer deaths from an incidence of 6,000 cancer cases. The FDA estimated only 300 cancer deaths. While this represents the most dramatic example of disparity from Gough's study, the EPA's estimation of total cancer risks still exceeded the FDA's by 13-30 percent.

[18] See Cass Sunstein, *Health-Health Tradeoffs*, 63 U Chi L Rev 1533, 1543-49 (1996).

criticism, but also legislative or executive interference.[19] Finally, unless agencies examine their regulations in a broad context, addressing one environmental risk may actually increase the danger posed by an ancillary risk. For example, reducing the risk of radiation poisoning by closing a nuclear power plant may increase the potential damage from acid rain as people burn more fossil fuels to compensate.[20]

3. *Inaccuracy.*

Finally, agency risk assessments may suffer from scientific inaccuracy.[21] This inaccuracy problem stems from two causes. First, agency risk calculations often mix both scientific and policy determinations.[22] Allowing scientific method to influence policy decisions aids rational decisionmaking, but allowing policy decisions to influence choice of scientific method may compromise the validity of the facts agencies employ in their determinations.[23] For example, the EPA and other agencies have placed such an emphasis on the need to appear scientifically credible that they will ground decisions exclusively on scientific data that may not "achieve the degree of reliability ordinarily required for valid scientific conclusions," simply because it is "scientific" data.[24] In addition, the process by which agencies calculate risk assessments is susceptible to political lobbying, producing an adversarial instead of scientific factual inquiry.[25] As a result, scientists on either side of risk assessment proceedings may not remain detached and impartial, but instead may represent parties with financial or ideological interests at stake.[26] Separating these interests from a factual inquiry requires a disinterested scientist, not a politically accountable policymaker.[27] In fact, as the failure of a proposed "Science Court" in the late 1960s indi-

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[19] Breyer, *Breaking the Vicious Circle* at 50 (cited in note 8).

[20] Sunstein, 63 U Chi L Rev at 1540 (cited in note 18).

[21] See, generally, Wagner, 96 Colum L Rev 1613 (cited in note 16).

[22] For example, agency determinations of "safe" levels of exposure to toxic chemicals may reflect not only a level of risk, but also the acceptability of that risk given current economic constraints. Milton Russell and Michael Gruber, *Risk Assessment in Environmental Policy-Making*, 236 Science 286, 288 (1987).

[23] Harold P. Green, *The Law-Science Interface in Public Policy Decisionmaking*, 51 Ohio St L J 375, 387 (1990).

[24] Latin, 5 Yale J Reg at 90 (cited in note 16).

[25] Id at 93. See also Green, 51 Ohio St L J at 387 (cited in note 23).

[26] Latin, 5 Yale J Reg at 93 (cited in note 16). See also Marcia Angell, *Science on Trial: The Clash of Medical Evidence and the Law in the Breast Implant Case* 50-68 (W.W. Norton 1996).

[27] Wagner, 96 Colum L Rev at 1628 (cited in note 16).

cates, even scientists might lack the capability to handle such a task.[28]

Second, agencies frequently lack sufficient data to support accurate risk assessments. Therefore, overstated risks may result from the number of assumptions agencies must make to compensate for this lack of data. For example, epidemiological studies, an important tool for toxic risk assessments, often lack rich, plentiful data.[29] Because of the risks of testing on humans, scientists must test toxin doses on animals.[30] Moreover, because the effects of low-level doses of a potential toxin may elude sophisticated measurement techniques, scientists perform tests with high-level doses instead.[31] An epidemiological study initially based on sparse data, extrapolated from tests involving high (rather than low) doses of toxins on animals (rather than humans) contains at least three potentially large sources of error. Worse, as already discussed, these errors do not merely add up, they multiply.[32] The existing regime may prove the best option in the face of massive uncertainty, but the lack of better alternatives does not excuse the unquestioning manner in which we accept its results.

II. JUDICIAL REVIEW OF AGENCY SCIENTIFIC DETERMINATIONS

A. Deference as Default: The Post-*Chevron* Mindset

So who does ensure that agencies do their jobs properly? Currently, each branch of the government assumes some responsibility. The executive branch retains the power to staff administrative agencies, which might provide a few incentives. However, those incentives occur before the agency makes any decisions, leaving the executive branch unresponsive to new agency actions. Congress may legislatively fine-tune agency decisions, or impose

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[28] Sheila Janasoff, *Science at the Bar: Law, Science, and Technology in America* 65-66 (Harvard 1995).

[29] McElveen and Amantea, 63 U Cin L Rev at 1584-86 (cited in note 2).

[30] Animals may respond differently to various toxins than humans, although scientists continue to better account for this difference. See Kenneth R. Foster, et al, eds, *Phantom Risk: Scientific Inference and the Law* 10-12 (MIT 1993); Graham, 14 Regulation at 16 (cited in note 12). See also McElveen and Amantea, 63 U Cin L Rev at 1584-86 (cited in note 2).

[31] Extrapolating from results of high dose tests to lower actual levels of exposure opens a source of error that regulators have yet to counter. See McElveen and Amantea, 63 U Cin L Rev at 1584-86 (cited in note 2); Graham, 14 Regulation at 16 (cited in note 12).

[32] See note 12 and accompanying text.

deadlines to spur agencies into action.[33] However, constant legislative oversight defeats the purpose of delegating the task in the first place. Finally, most affected private parties rely on the courts. Unfortunately, judicial review faces its own limitations.

First, obtaining judicial review of an agency's risk determinations poses procedural difficulties. Plaintiffs must begin by establishing standing under the Administrative Procedure Act ("APA").[34] Then, they must establish that the agency action at issue is a "final agency action," and therefore reviewable by the courts.[35] Traditionally, reviewability does not pose an insurmountable obstacle. However, when plaintiffs challenge an agency's use of scientific data, they often face non-final agency decisions.

Assuming plaintiffs can jump these procedural hurdles, they still must face a substantive obstacle. Currently, courts follow an extremely deferential standard of review for EPA determinations of environmental risk. The APA dictates that a court may set aside agency action only if it finds it "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."[36] This legislatively-mandated deference is strongest when the agency interprets a statute. As the Supreme Court ruled in *Chevron, U.S.A., Inc. v Natural Resources Defense Council, Inc.*, if a "statute is silent or ambiguous with respect to the specific issue [the agency must decide], the question for the court is whether the agency's answer is based on a permissible construction of the statute."[37] Of course, the limits of language being what they are, most statutes are either silent or ambiguous with respect to almost any issue.[38] Agencies therefore enjoy great discretion in

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[33] Robert Glicksman and Christopher H. Schroeder, *EPA and the Courts: Twenty Years of Law and Politics*, 54 L & Contemp Probs 249, 253 (1991).

[34] 5 USC § 701 et seq (1994). Courts have often construed the APA to allow private citizens to challenge EPA actions. See, for example, *McDowell v Schlesinger*, 404 F Supp 221 (W D Mo 1975). However, a host of issues remains in determining standing, including whether an agency has actually taken an action, whether the harm is an injury in fact, and whether the parties meet the specific requirements of the general statute. For a good introduction to standing issues under the APA, see E.P. Krauss, *Unchecked Powers: The Supreme Court and Administrative Law*, 75 Marq L Rev 797, 826-36 (1992).

[35] *Franklin v Massachusetts*, 505 US 788, 797 ("The core question is whether the agency has completed its decisionmaking process, and whether the result of that process is one that will directly affect the parties"). See also Note, *Reviewability of Environmental Impact Statements on Legislative Proposals After* Franklin v Massachusetts, 80 Cornell L Rev 413 (1995).

[36] 5 USC § 706(2)(A).

[37] 467 US 837, 843 (1984).

[38] See, for example, Richard A. Posner, *The Problems of Jurisprudence* 262-69 (Harvard 1990); Cass R. Sunstein, *After the Rights Revolution: Reconceiving the Regulatory*

interpreting the statutes they administer. Additionally, in ruling that the agency's answer must rest on a "permissible construction," the Court stressed that a court could not substitute its own judgment for the agency's determination.[39] Therefore, judicial review does not allow finding the best solution possible—rather, the court may only accept or reject the proposed scheme. Faced with the binary choice between affirming or negating (but not modifying) a borderline regulation, courts usually affirm agency interpretations. In fact, one empirical study has demonstrated that this deference to agency interpretations has grown pervasive enough for one to consider it the default for judicial review.[40]

B. Judicial Deference and Questions of Fact

Unfortunately, while deference to agency interpretations of law seems straightforward after *Chevron*, courts confront a large obstacle in determining exactly when that level of deference is appropriate. Most agency decisions are not solely legal questions, but "mixed" questions of both law and fact, and courts face a very real tension in choosing between exhibiting "deference" and simply "rubber-stamping" these decisions.[41] Historically courts have seemed confused as to the degree of examination either allowed or required under the "arbitrary and capricious" standard.

This confusion is greatest when the agency must decide questions involving both legal and factual issues. Possibly because of the blurry line between science and policy, courts frequently have assumed that an "arbitrary and capricious" standard of review requires deference to the agency's expertise in making factual determinations as well as in its interpretation of the law.[42] This approach finds support in dicta from the Su-

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State 116-17 (Harvard 1990).

[39] 467 US at 843-44 ("In such a case, a court may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of an agency.").

[40] Peter H. Schuck and E. Donald Elliott, *To the* Chevron *Station: An Empirical Study of Federal Administrative Law*, 1990 Duke L J 984, 1058-59 (finding a 15% increase in affirmances and a 40% decline in remand/reversals following the *Chevron* decision).

[41] For a succinct statement of this dilemma in a factfinding, rather than a *Chevron*, context, see *Lead Industries Assn, Inc. v EPA*, 647 F2d 1130, 1145 (DC Cir 1980).

[42] See *Reynolds Metals Co. v EPA*, 760 F2d 549, 559 (4th Cir 1985) (" . . . an agency's data selection and choice of statistical methods are entitled to great deference."); *The Connecticut Fund for the Environment, Inc. v EPA*, 696 F2d 169, 177 (2d Cir 1982) (deferring to "the Agency's technical expertise" on the question of whether it could model the effect of one pollutant on other pollutants).

preme Court's decision in *Baltimore Gas & Electric Co. v Natural Resources Defense Council, Inc.*:

> [A] reviewing court must remember that the Commission is making predictions, within its area of special expertise, at the frontiers of science. When examining this kind of scientific determination, as opposed to simple findings of fact, a reviewing court must generally be at its most deferential.[43]

Opposing this line of thought, several Circuit Courts of Appeals have held that, while courts must defer to final agency determinations of risk, they also must review the facts the agency used in arriving at that decision as carefully as they would any other agency decisions.[44] This conflict between deference to factual findings and probing inquiry of evidence is important to resolve. On the one hand, if the EPA can make scientific determinations knowing its reasoning will never undergo review, it faces fewer incentives to make sound decisions.[45] At the same time, the EPA, like other administrative agencies, exists to render highly technical judgments that the legislature and (non-administrative) executive are poorly qualified to make.[46] Given this need for specialization, it seems logical that courts should defer to the EPA's expertise when it acts in its bailiwick.

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[43] 462 US 87, 103 (1983). See also *National Coalition Against the Misuse of Pesticides v EPA*, 867 F2d 636, 645 (DC Cir 1989) (finding agency settlement with pesticide manufacturer reasonable in face of Administrator's assertion that scientific controversy existed as to risk of chlordane use).

[44] See *Natural Resources Defense Council, Inc. v EPA*, 902 F2d 962, 968 (DC Cir 1990) (stating that while the court "must defer to the agency's interpretation of equivocal evidence so long as it is reasonable," it "must, nevertheless, carefully review the record to ascertain that the agency has made a reasoned decision based on 'reasonable extrapolations from some reliable evidence.'"); *National Coalition Against the Misuse of Pesticides v Thomas*, 809 F2d 875 (DC Cir 1987) (finding the EPA's reversal on proper pesticide exposures in mangoes "arbitrary and capricious" because it lacked "adequate support" in the record). This emphasis on a "hard look" at the facts underlying agency decisions predates *Chevron*. See, for example, *Lead Industries Assn, Inc. v EPA*, 647 F2d 1130, 1145 (DC Cir 1980) ("[T]he court must undertake a 'substantial inquiry' into the facts, one that is 'searching and careful.'"); *Cincinnati Gas & Electric Co. v EPA*, 578 F2d 660, 664 (6th Cir 1978) (holding EPA determination "arbitrary & capricious" because it ignores all the scientific evidence before the agency).

[45] See, for example, Patricia Smith King, *Applying* Daubert *to the "Hard Look" Requirement of NEPA: Scientific Evidence Before the Forest Service in* Sierra Club v Marita, 2 Wis Envir L J 147, 157 (1995).

[46] John S. Applegate, *Worst Things First: Risk, Information and Regulatory Structure in Toxic Substances Control*, 9 Yale J Reg 277, 289-95 (1992).

This conflict grows even more pronounced in the context of risk assessment. Unlike other agency decisions, risk assessment possesses some characteristics that make judicial review especially difficult. First, risk assessment involves a conscious blending of scientific fact and policy judgment. As a result, determining which portions of a risk assessment courts may actually review becomes especially daunting. Second, given the paucity of reliable data on newer, unforeseen risks, courts face a natural temptation to defer to agencies as much as possible when deciding which data an agency may consider.

III. APPLYING *DAUBERT* TO EPA DETERMINATION

Courts may resolve the conflict between deference to final EPA determinations of policy and scrutiny of the science upon which the EPA based those decisions by stepping outside of the administrative law paradigm and looking to the Supreme Court's recent evidentiary decision, *Daubert v Merrell Dow Pharmaceuticals, Inc.* .[47] Applying the admissibility test for scientific expert testimony under *Daubert* may help to preserve the advantages of both deference to policy and scrutiny of science.

In order to understand fully why applying the *Daubert* standard helps to resolve the conflict between necessary deference to agency expertise and judicial checks on unfettered agency discretion, it is first important to examine the background of the *Daubert* case itself.

A. *Daubert*

Daubert v Merrell Dow Pharmaceuticals, Inc., involved a challenge to the longstanding "general acceptance" test for scientific evidence articulated by the D.C. Circuit Court of Appeals in *Frye v United States*.[48] James Alphonso Frye, a murder defendant, attempted to introduce evidence of his innocence via the results of a "systolic blood pressure deception test," essentially a crude precursor to the polygraph.[49] The prosecution challenged the admissibility of both the test results and the testimony of the administering scientist.[50] The court ruled that while "[j]ust when a scientific principle or discovery crosses the line between

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[47] 509 US 579 (1993).
[48] 293 F 1013 (DC Cir 1923).
[49] Id.
[50] Id at 1014.

the experimental and demonstrable stages is difficult to define . . . ,"[51] the principle or discovery "must be sufficiently established to have gained general acceptance in the particular field in which it belongs."[52] This "general acceptance" test became the norm for determining the admissibility of scientific evidence until 1993.[53] The general acceptance test offered distinct advantages. It was easy to administer, did not require judges to moonlight as scientists, and worked reasonably well at screening out "junk science."[54] The test suffered from a distinct disadvantage as well. Depending on the judge wielding the test, it either precluded valid but innovative scientific theories because they had not yet reached the level of "general acceptance," or it proved utterly useless as judges allowed evidence on the premise that someone had to be the first to espouse an innovative, though not yet proven, theory.[55] In the context of this debate over scientific rigor, the *Daubert* case appeared.

The litigation in *Daubert* concerned infants suffering from limb reduction birth defects allegedly resulting from their mothers' use of Benedictin, an antinausea drug marketed by Merrell Dow.[56] After extensive pretrial discovery, Merrell Dow moved for summary judgment because no evidence existed demonstrating Benedictin to be a human teratogen.[57] In support of its motion, Merrell Dow attached an affidavit by an expert on toxicology stating that a careful review of the scientific literature

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[51] Id.

[52] 293 F at 1014.

[53] See, for example, Edward J. Imwinkelreid, *The Methods of Attacking Scientific Evidence* §4-5 (Michie 2d ed 1992).

[54] At least, most of the time. For a stinging late *Frye*-era critique of how judges became unable to distinguish between genuine innovators and quacks, see Peter W. Huber, *Galileo's Revenge: Junk Science in the Courtroom* 14-17 (Basic 1991).

[55] See, for example, Judge Stern's concurring opinion in *Rubanick v Witco Chemical Corp.*, 576 A2d 4 (NJ 1990):

> There always has to be a first; someone must be an innovator. Yet, I suppose that Christopher Columbus could never have been qualified as an expert to render an opinion on circumnavigation, and the Wright brothers would never have been able to testify as experts and give opinions relating to flight because, for much of their day, their views never gained "general acceptance within the scientific community."

Id at 15 (citations omitted).

[56] 509 US at 582. For an examination of the scientific disputes underlying Benedictin litigation, see Louis Lasagna and Sheila R. Shulman, *Benedictin and the Language of Causation*, in Kenneth R. Foster, et al, eds, *Phantom Risk: Scientific Inference and the Law* 101 (MIT 1993).

[57] 509 US at 582. A teratogen is a substance capable of causing malformations in a human fetus, leading to birth defects.

on Benedictin failed to show any teratogenic effects.[58] The plaintiffs countered Merrell Dow's expert testimony that Benedictin was safe with expert testimony of their own. Using animal studies, pharmacological studies, and "reanalysis of previously published epidemiological studies," they argued Benedictin was teratogenic.[59] Despite the conflicting testimony, the District Court granted summary judgment for Merrell Dow, finding the plaintiffs' expert testimony inadmissible because the methods employed were not sufficiently established to receive general acceptance.[60] The Ninth Circuit Court of Appeals affirmed on appeal, explicitly citing the *Frye* general acceptance test as the basis for its decision.[61]

The Supreme Court held that the enactment of the "more liberal" Federal Rules of Evidence ("FRE") in 1975, especially Rule 702 concerning expert testimony, superseded the *Frye* "general acceptance test."[62] As a result, the Court remanded the case for further consideration using FRE 702 instead of the *Frye* general acceptance test.[63]

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[58] Id.

[59] Id. at 583.

[60] *Daubert v Merrell Dow Pharmaceuticals, Inc.*, 727 F Supp 570, 572 (S D Cal 1989). In rejecting the evidence, the District Court stated, "There are two schools of thought governing expert testimony in these Benedictin cases, and one seems to be prevailing in the Federal Courts. Unfortunately for the plaintiffs, the prevailing school of thought warrants summary judgment [against them] in this case." Id. Interestingly, the rationale the District Court used did not mention *Frye* explicitly, but rather claimed that Federal Rule of Evidence 703 restricted the admissibility of scientific evidence to that which has "general acceptance." Id. Rule 703 states:

> The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible into evidence.

FRE 703. Apparently, the District Court misread FRE 703's hearsay exception (allowing hearsay if "of a type reasonably relied on by experts . . . ") as requiring the general acceptance test for *all* evidence. In addition, the District Court stated that it must "critically evaluate" the experts' reasoning process, but then claimed that "absent a scientific understanding" of Benedictin's effects, the plaintiffs would have to establish causation via epidemiological evidence, the "generally accepted" method in Benedictin litigation. *Daubert*, 727 F Supp at 572, 575.

[61] *Daubert v Merrell Dow Pharmaceuticals, Inc.*, 951 F2d 1128, 1129 (9th Cir 1991).

[62] 509 US at 587-88. Rule 702 provides, in relevant part:

> If scientific, technical or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

FRE 702.

[63] 509 US at 597.

However, the *Daubert* Court offered the District Court further guidance. It ventured several "observations" to consider in determining the admissibility of scientific evidence that later courts have adopted as required.[64] First, a court must determine "whether the reasoning or methodology underlying the testimony is scientifically valid and [ ] whether that reasoning or methodology properly can be applied to the facts in issue."[65] In evaluating the scientific validity of the evidence, courts should consider: (1) whether the methodology can be proven wrong;[66] (2) whether the method has undergone publication and peer review;[67] (3) the method's known or potential rate of error;[68] and even (4) whether the method enjoys general acceptance.[69] Subsequent Circuit Court of Appeals decisions have added other factors for district courts to consider.[70] Second, a judge must determine whether the proffered evidence "properly can be applied to the facts at issue," a characteristic courts call "fit."[71] When evaluating regulation, courts have considered reliability more important than fit, in part because they view the determination of fit as a question of policy rather than science.[72]

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[64] See notes 66-72 and accompanying text, infra.

[65] 509 US at 592-93.

[66] Id at 593. The Court referred to this characteristic as "falsifiability."

[67] Id. Later courts have stressed that publication of the particular method is not a necessary prerequisite for admissibility. See *Chikovsky v Ortho Pharmaceutical Corp.*, 832 F Supp 341, 345 n 5 (S D Fla 1993) (citing *Daubert*).

[68] 509 US at 594.

[69] Id. This consideration is the same as the *Frye* general acceptance test, but now numbers only one of many factors a court should consider.

[70] The Third Circuit enumerated several other criteria, including " . . . (4) the existence and maintenance of standards controlling the technique's operation; . . . (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; (8) the non-judicial uses to which the method has been put." *In re Paoli Railroad Yard PCB Litigation*, 35 F3d 717, 742 n 8 (3d Cir 1994). See also *Wade-Greavy v Whitehall Laboratories, Inc.*, 874 F Supp 1441, 1478 (D VI 1994) (considering "the qualifications and professional stature of the expert witnesses employing the methodology"). The Seventh Circuit has stressed language in *Daubert* suggesting that testimony based on a scientific method, must "rule out 'subjective belief or unsupported speculation.'" *Porter v Whitehall Laboratories, Inc.*, 9 F3d 607, 613 (7th Cir 1993) (citing *Daubert*). See also *O'Connor v Commonwealth Edison Co.*, 13 F3d 1090, 1106-07 (7th Cir 1994) (rejecting witness's unsupported contention that he could identify radiation-induced cataracts from mere observation). Other factors courts have considered include logical consistency, consistency with accepted theories, and degree of precision. See *In re TMI Litigation Cases Consolidated II*, 911 F Supp 775 (M D Pa 1996). Commentators have urged using such other considerations as the existence of a specialized literature and the extent to which a technique relies on the expert's subjective interpretation. See Joseph Sanders, *Scientific Validity, Admissibility, and Mass Torts After* Daubert, 78 Minn L Rev 1387, 1396 n 43 (1994).

[71] 509 US at 592.

[72] See, for example, *Paoli Railroad Yard*, 35 F3d at 746; *Cavallo v Star Enterprise*,

Courts remain reluctant to decide scientific facts for agencies. The closest any court has come to reviewing an agency's scientific determination was in *Buchholz v Dayton International Airport*,[73] which involved a citizen suit to enjoin the airport's use of certain de-icing chemicals and force it to pay for the costs of safe drinking water in the interim.[74] The defendant airport used EPA drinking water standards to argue it had not impermissibly polluted drinking water with ethylene glycol.[75] The plaintiffs' toxicologist challenged the validity of the standards, but the District Court allowed the evidence based on his own admission that the document establishing the standards was both "scientifically sound and peer reviewed."[76]

This reluctance by plaintiffs and courts to apply the *Daubert* standards to agency decisions based on scientific data is puzzling. There is certainly no compelling reason not to use the *Daubert* standards to review the science behind agency risk assessments, and both precedent and common sense dictate their application.

B. Applying *Daubert*: Agency Records as Expert Testimony under Federal Rule of Evidence 703

When examining agency decisions under the Administrative Procedure Act ("APA"),[77] courts shall "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law . . . ."[78] Under the APA, courts may examine any agency decision either in a special statutory review proceeding or, if such a proceeding does not exist, in an applicable action, including declaratory judgments and injunctions.[79] Private parties have challenged EPA actions mainly through this second option.

However, such challenges take place at the appellate level rather than in a trial court, forcing the question: do the Federal Rules of Evidence govern such review? Ordinarily, because ad-

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892 F Supp 756, 762 (E D Va 1995).

[73] 1995 WL 811897 (S D Ohio).

[74] Id at *6.

[75] Id at *27.

[76] Id. Because the plaintiff's expert essentially conceded the document's admissibility, the court did not have to decide whether the *Daubert* standards would apply to an agency determination of risk.

[77] 5 USC § 701 et seq (1994).

[78] 5 USC § 706(2)(A).

[79] 5 USC § 703.

ministrative adjudications are not jury trials, courts do not consider agencies bound by the FRE.[80] However, as Kenneth Davis and Richard Pierce, Jr. point out in their *Administrative Law Treatise*, "to the extent that the FRE announce any policy relevant to the rules of evidence [governing administrative law], that policy is contained in Rule 703."[81] Focusing a judicial inquiry in this manner implies that the courts should treat an agency as an expert in its field. Experts receive great deference from courts, as expressed in both Rules 702 and 703, but that deference has limits. *Daubert* helps describe those limits.

Why treat agencies like testifying experts? Mainly because the analogy is extremely apt. When agencies justify their regulation of risk to courts, they must offer evidence from the record to justify their regulatory decisions. The evidence they offer in support of those regulations will contain, at least in part, the agency's assessment of the risk regulated. Agencies must use risk assessments to lay a foundation for the ultimate decision they make. In that sense a risk assessment operates as expert testimony, designed to help the factfinder make the appropriate determinations of fact. It operates, in the words of FRE 702, to "assist the trier of fact to understand the evidence or determine the fact in issue."[82] Because "the party presenting the expert must show that the expert's findings are based on sound science,"[83] the agency must provide evidence from the record justifying its decision.

However, the fact that FRE 702 and 703 may apply to agency risk determinations does not mean they should always apply. The court must still decide whether risk assessments represent factual or policy judgments. If they are factual, then the court must determine their admissibility. If they are policy, then the court must defer to the agency's judgment. In *Baltimore Gas & Electric Co. v Natural Resources Defense Council, Inc.*, the Supreme Court drew a distinction between a "scientific determination" and "simple findings of fact."[84] But in *Baltimore Gas & Electric Co.*, the Court was dealing with predictions where little

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[80] Kenneth Culp Davis and Richard J. Pierce, Jr., 2 *Administrative Law Treatise* §§ 10.1-10.3 (Little, Brown 3d ed 1994).

[81] Id § 10.2 at 120.

[82] FRE 702.

[83] *Daubert v Merrell Dow Pharmaceuticals, Inc.*, 43 F3d 1311, 1316 (9th Cir 1995) ("*Daubert II*").

[84] 462 US 87, 103 (1983).

scientific evidence existed—at the "frontiers of science."[85] Once the question retreats from the frontier, scientific determinations become simple findings of fact, and may be treated accordingly. In the landmark case *Industrial Union Department, AFL-CIO v American Petroleum Institute* ("*The Benzene Case*"), the Supreme Court overruled the Occupational Safety and Health Agency's ("OSHA") risk assessment for benzene exposure in part because it was based not on any scientific process, but on a "series of assumptions" indicating a risk of leukemia incidence at 10 parts per million.[86]

Post-*Benzene* cases have followed this principle of according deference to agency decisions, so long as the evidence can withstand "hard look" scrutiny. In *National Coalition Against the Misuse of Pesticides v Thomas*, the D.C. Circuit reversed the EPA's determination of proper pesticide exposure levels because the EPA's decision to modify the levels from 0 parts per billion (ppb) to 30 ppb (1) rested on statutorily impermissible factors,[87] and (2) lacked adequate support in the record.[88] The D.C. Circuit did not hold that the EPA could not find facts justifying its decision, merely that the assertions offered in its briefs could not suffice.[89]

Later, in *Natural Resources Defense Council, Inc. v EPA*, the D.C. Circuit ruled that while an agency's interpretation of equivocal facts commands deference, that interpretation must rest on both reasonable inferences and reliable evidence.[90] While in this particular case, the D.C. Circuit upheld the EPA's Revisions to National Ambient Air Quality Standards,[91] the specific review the court engaged in involved surveying multiple studies of the effects of air pollution over a sixteen year period.[92]

Even courts that have deferred to an agency's finding of facts without examining the record have done so in situations where no scientific evidence existed compelling a decision to regulate or not. In *Connecticut Fund for the Environment, Inc. v EPA*, the Second Circuit reviewed the EPA's approval of more permissive

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[85] Id.

[86] 448 US 607, 634 (1980).

[87] 809 F2d 875, 882 (DC Cir 1987). The EPA had considered the economic impact of its decision on foreign countries.

[88] Id.

[89] Id.

[90] 902 F2d 962, 968-69 (DC Cir 1990).

[91] Id at 976.

[92] Id at 968-73.

sulfur emissions standards in fuels burned by state agencies.[93] In noting that no model existed to allow the EPA to predict the effect of sulfur emissions on other states, the court pointed out that "it would be unwise to order the Agency to consider effects it cannot accurately measure . . . or to hold that its failure to do so was an abuse of discretion."[94] Similarly, in *Reynolds Metal Co. v EPA*, the Fourth Circuit upheld EPA effluent limitations because it considered the scientific determinations the agency made beyond the court's competence.[95] Specifically, the court called technological and scientific issues "by their very nature difficult to resolve by traditional principles of judicial decisionmaking."[96] In a pre-*Daubert* world, this assertion was almost certainly true. After *Daubert*, intelligible principles exist for determining admissibility, and courts consider themselves qualified to employ those principles.[97]

Courts may competently use the *Daubert* factors primarily because they already must use them to examine the admissibility of evidence into the record for the purposes of determining whether the EPA's conclusion rests on "substantial evidence."[98] Thus, the judge would not second-guess the agency's conclusion, but simply ensure that the conclusion rests on evidence in the

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[93] 696 F2d 169, 172 (2d Cir 1982).

[94] Id at 177 (citations omitted).

[95] 760 F2d 549, 559 (4th Cir 1985).

[96] Id at 558-59.

[97] See *In Re TMI Litigation Cases Consolidated II*, 922 F Supp 1038, 1050 (M D Pa 1996) (dismissing risk assessment expert's testimony as based on unreliable data). In dismissing Dr. Zakrzewski's testimony for this portion of the TMI litigation, the district court relied on risk assessment guidelines propagated by "several internationally respected organizations," including the National Academy of Sciences. Id. The court dismissed the risk assessment because it could not find "even an elementary resemblance between Dr. Zakrzewski's methodology and any of the internationally recognized methodologies." Id.

[98] 5 USC § 706(2)(E) (1994). See also *National Coalition Against the Misuse of Pesticides v EPA*, 867 F2d 636, 642 (DC Cir 1989) ("[T]he Administrator satisfies his burden of production by proffering 'substantial evidence' of harm from respected scientific sources."); *Reynolds Metal Co. v EPA*, 760 F2d 549, 558 (4th Cir 1985). This application of *Daubert* to agency evidence significantly differs from that proposed by Patricia Smith King in *Applying* Daubert *to the "Hard Look" Requirement of NEPA: Scientific Evidence Before the Forest Service in* Sierra Club v Marita, 2 Wis Envir L J 147 (1995). King argues that the courts should use the *Daubert* standards to comparatively evaluate the evidence that existed before the agency at the "hard look" stage. 2 Wis Envir L J at 156-57. King's aggressive approach would allow the court to substitute its own judgment for the agency's by finding one party's evidence "better" than the other's via application of the *Daubert* factors. Applying *Daubert* for its original gatekeeping purpose, on the other hand, does not second guess the EPA—it merely ensures that the inquiry into whether a decision was "arbitrary and capricious" consistently rests on the same balance between deference and skepticism.

record that meets the same threshold standards as the other scientific evidence before the court. In fact, if the court did not examine agency evidence under the *Daubert* factors, it would force plaintiffs challenging an agency decision to meet evidentiary standards that the agency itself could ignore. Provided the EPA's evidence meets the initial threshold of acceptability under *Daubert*, its final determination would then receive the deference required under the APA. Applying the *Daubert* gatekeeping function therefore allows courts to check the validity of the agency's reasoning while maintaining the proper amount of deference to the agency's rulemaking and adjudicative powers.

For example, in *Reynolds Metal*, the Fourth Circuit concluded that the EPA's scientific judgments deserved deference because the court could not second-guess the science the EPA used.[99] However, reviewing the court's examination of the record reveals two points at which applying *Daubert* would have afforded the searching factual inquiry such decisions require. First, the plaintiffs asserted that the EPA had miscalculated the effluent concentrations of TTO, a toxic grease remover, in setting the acceptable levels of TTO.[100] The court blandly deferred to the EPA's assertion that the error was immaterial.[101] Under *Daubert*, if the allegation were true, the court would have reason to question the EPA's risk assessment because of an elevated rate of error.[102] While this problem would most likely not prove fatal to the EPA's assessment, it certainly deserves the court's attention. Second, the plaintiffs disputed the EPA's method of collecting data in determining the threat TTO posed.[103] The Fourth Circuit immediately deferred to the EPA because it had conceded that its sampling was not designed for scientific accuracy.[104] Assuming for a moment that the plaintiffs could demonstrate what proper sampling methods would be, the court would have to reject the EPA's assessment for three reasons: (1) it contained a large potential source of error,[105] (2) the method of da-

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[99] 760 F2d at 559.
[100] Id at 559-60.
[101] Id.
[102] *Daubert*, 509 US at 594.
[103] *Reynolds Metal*, 760 F2d at 561.
[104] Id.
[105] *Daubert*, 509 US at 594.

ta selection was not falsifiable,[106] (3) the method of data selection had not undergone peer review.[107]

In cases where courts might rubber-stamp an agency risk assessment because the litigation has devolved into a swearing contest between the agency and the plaintiff, the *Daubert* factors allow for a more rational method of ensuring decisions are not arbitrary or capricious than immediate deference to the agency on questions of fact.

C. The Efficacy of *Daubert*: Judicial Review as Agency Check

Allowing for a *Daubert* check forces agencies to make regulatory decisions transparently. If agencies know that courts will examine their methods, then they have an incentive to correct the false assumptions or overly cautious estimates from which they start. In addition, applying the *Daubert* standard requires agencies to explicitly indicate whether they have relied on science or policy to justify a decision. Agency policy requires deference. Agency science can and should be checked.

For example, the *Daubert* standard requires courts to examine the known or potential rate of error for a given piece of expert testimony.[108] That examination does not necessarily require the courts to be experts in error rates or statistics themselves, but it does require them to know whether they understand what a litigant has provided them.[109] If an intelligent layperson can understand the evidence, then the judge may rule on admissibility. Use of unintelligible technical jargon should not shield an agency from judicial scrutiny.

The most compelling objection to this scheme argues that it requires judges to be scientists. Judge Kozinski expressed this criticism eloquently during the Ninth Circuit's consideration of *Daubert* on remand, complaining that "though we are largely untrained in science and certainly no match for any of the witnesses whose testimony we are reviewing, it is our responsibility to determine whether those experts' proposed testimony amounts to

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[106] Id at 593.

[107] Id.

[108] 509 US at 594.

[109] See, for example, *In re TMI Litigation Cases Consolidated II*, 922 F Supp 997, 1016-19 (M D Pa 1996) (criticizing plaintiffs for obscuring statistical significance of proffered expert's cancer reanalysis).

'scientific knowledge,' constitutes 'good science,' and was 'derived by scientific method.'"[110]

Judge Kozinski is not a lone voice in the wilderness. Commentators have voiced concern about judges' scientific aptitude since the Court first decided *Daubert*.[111] If one worries about judges' not knowing enough about science to begin with, the argument runs, why allow them to overrule a specialist's scientific judgment? One can imagine this argument carries even greater force when a judge reviews an agency's determination of risk. In that case, not only does the judge lack expertise, but a standard of deference to agency determinations already exists. A related concern argues that judges will (or do) apply more restrictive standards to scientific determinations under *Daubert* because they find it easier to exclude confusing or new evidence than to actually sift through it to determine its validity.[112]

These critics fail to realize that the judge does not substitute her judgment for the agency's but merely acts in a "gatekeeper" capacity—forcing the agency to live up to the same standards as any other litigant where scientific evidence is in dispute. The judge inquires into the admissibility of the agency's scientific evidence, but not its sufficiency. Those two inquiries pose very different questions, and the admissibility question proves far easier to answer. As the Second Circuit stated in *Mairana v United States Mineral Products Co.*, "Admissibility entails a *threshold* inquiry over whether a certain piece of evidence ought to be admitted at trial. . . . A sufficiency inquiry . . . asks whether the collective weight of a litigant's evidence is adequate to present a jury question . . . ."[113]

In addition, judges are not without guidance in assessing admissibility. *Daubert* itself provides several non-technical guidelines for the initial assessment of the validity of scientific evidence. Judges also have recourse to references like the Federal Judicial Center's *Reference Manual on Scientific Evidence*.[114] In sum, judges would not have to become scientific experts to rule on the admissibility of scientific evidence—they would merely have to be judges.

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[110] *Daubert II*, 43 F3d at 1316.

[111] See, for example, Wayne Roth-Nelson and Kathey Verdeal, *Risk Evidence in Toxic Torts*, 2 Envir Lawyer 405, 435-37 (1996) (arguing most judges lack scientific expertise to review the relevance and reliability of scientific evidence).

[112] Sanders, 78 Minn L Rev at 1429 (cited in note 70).

[113] 52 F3d 1124, 1132 (2d Cir 1995) (emphasis in original).

[114] Federal Judicial Center, *Reference Manual on Scientific Evidence* (FJC 1994).

Others object that the quality of data required for regulation differs from that required for litigation.[115] Specifically, data used for preventive regulation need not and should not meet the same rigorous standards as data used in establishing causation in a toxic tort suit.[116] However, as already argued, application of the *Daubert* standard imposes a threshold test for admissibility, not a test of the comparative weight of evidence. It is difficult to imagine a situation in which an agency could offer no data to support its decision to regulate risks that could meet the minimal *Daubert* threshold. In fact, one might argue that courts should consider a decision based on no or incompetent data "arbitrary and capricious" on its face.

Leaving aside the objections to the court's ability to find scientific fact, still other reasons exist to give a *Daubert*-style review function to the courts. Courts may be the most effective means of checking agency mistake or self-interest. The legislature will likely respond to interest-group pressure and treat statutes giving agencies guidance as yet another method of providing pork to their constituents.[117] The executive branch, while politically accountable to a national constituency rather than a series of local ones, suffers from self-interest as well. If executive agencies formulate the standards, the executive branch will likely seek to uphold them even if they prove inferior or based on substandard science.

Finally, while applying *Daubert* to judicial review of risk assessments helps to make the regulation of environmental risks more rational, it does so with a minimum of disruption to the current administrative regime. The largest problem with many calls for risk reform is that they require revolutionary changes to effect their desired result.[118] Applying *Daubert* imposes no

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[115] Bernard D. Goldstein, *Risk Assessment and the Interface Between Science and Law*, 14 Colum J Envir L 343, 351 (1989).

[116] Id. Contrast Patricia Smith King's argument that regulatory agencies should use the exact same evidence as that proffered in federal court. 2 Wis Envir L J at 156 (cited in note 98).

[117] Basically, Congress will likely provide "guidance" to agencies that proves beneficial to constituents from individual districts by, for example, interpreting a statute to provide an exemption for a federally funded project or constituent industry. See Robert Glickman and Christopher H. Schroeder, *EPA and the Courts: Twenty Years of Law and Politics*, 54 L & Contemp Probs 249, 286 (1991) ("It would appear that the senators saw little distinction between the Clean Air Act and a fight over which defense installations to close, or an appropriation for public works projects. The pork tastes as good, from whichever barrel it comes.").

[118] See, for example, John S. Applegate, *A Beginning and Not an End in Itself: The Role of Risk Assessment in Environmental Decision-Making*, 63 U Cin L Rev 1643, 1672-74

grand new vision on the present regulatory regime—it neither dramatically enlarges nor drastically restricts the role of government in regulating risk. What it does do is make regulation more effective by eliminating the most likely, and most preventable, sources of potential error.

CONCLUSION

The EPA faces a number of challenges in its attempts to regulate environmental problems. While the difficulties posed by absurd regulatory results, inconsistent valuation of risks, and scientific inaccuracy in risk assessment are deeply ingrained in the regulatory system, it is possible to alleviate these problems in part by enhancing the effectiveness of judicial review of agency decisions. This Comment has argued that applying the *Daubert* standard of admissibility for scientific evidence in cases challenging agency regulatory decisions best preserves the balance between the deference to agency policy commanded by the Supreme Court and the judicial skepticism necessary to ensure that courts are not mere rubber stamps for environmental policy. Applying *Daubert* gives the courts both the power and the guidance to examine the validity of the facts undergirding regulation of environmental risk, without sacrificing the ability of the EPA to independently make that policy.

Regulation of environmental risk remains a priority for the United States. Applying the *Daubert* standards of scientific validity to the review of that process ensures that environmental regulation rests on rational, falsifiable, correctable bases. By keeping the regulatory process scientific, *Daubert* helps to keep it effective.

(1995) (arguing for overhaul of environmental legislation as a whole); Mark Eliot Shere, *The Myth of Meaningful Risk Assessment*, 19 Harv Envir L Rev 409, 480-91 (1995) (arguing regulators should focus on environmental ethics and "quality of life" rather than quantifiable public health risks); Stephen Breyer, *Breaking the Vicious Circle: Toward Effective Risk Regulation* 55-81 (Harvard 1993) (proposing centralized bureaucratic oversight group); Donald T. Horstein, *Reclaiming Environmental Law: A Normative Critique of Comparative Risk Analysis*, 92 Colum L Rev 562, 629-33 (1992) (arguing that regulators should consider questions of equity among risk bearers and obligations to other species).